COUNTY OF LOS ANGELES
Public Health

JONATHAN E. FIELDING, M.D., M.P.H.
Director and Health Officer

JONATHAN E. FREEDMAN
Chief Deputy Director

313 North Figueroa Street, Room 806
Los Angeles, California 90012
TEL (213) 240-8117 • FAX (213) 975-1273

www.publichealth.lacounty.gov

ADOPTED
BOARD OF SUPERVISORS
COUNTY OF LOS ANGELES

#32 APRIL 19, 2011

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April 19, 2011

The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

APPROVAL TO ACCEPT A SUBAWARD FROM THE ASSOCIATION OF PUBLIC HEALTH LABORATORIES FOR TUBERCULOSIS NUCLEIC ACID AMPLIFICATION TESTING FOR THE PERIOD OF JANUARY 1, 2011 THROUGH JUNE 30, 2011 (ALL SUPERVISORIAL DISTRICTS)(3 VOTES)

SUBJECT

Request approval to accept a Subaward from the Association of Public Health Laboratories for Tuberculosis Nucleic Acid Amplification Testing and delegate authority to accept and execute future awards and/or amendments.

IT IS RECOMMENDED THAT YOUR BOARD:

1. Approve and instruct the Director of the Department of Public Health (DPH), or his designee, to accept and execute a Subaward Agreement from the Association of Public Health Laboratories (APHL), Exhibit I, for Tuberculosis (TB) Nucleic Acid Amplification Testing (NAAT), for the period of January 1, 2011 through June 30, 2011, in the amount of $114,080, at no net County cost.

2. Delegate authority to the Director of DPH, or his designee, to accept future awards and/or amendments from APHL that are consistent with the requirements of the Subaward that extend the term of funding through December 31, 2014, allow for the rollover of unspent funds and/or redirection of funds, adjust the term of the Subaward through March 31, 2015, and/or provide an increase or decrease in funding up to 25 percent above or below each award year's annual base amount, subject to review and approval by County Counsel, and notification to your Board and the Chief Executive Office.

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

The recommended actions will allow DPH to accept the APHL Subaward and future awards and/or amendments from APHL to fund new state-of-the art technology that will enhance diagnosis and improve treatment options for tuberculosis. Funding will also support the purchase of new equipment and supplies necessary to implement two new NAAT procedures, conduct verification studies, and support initial testing services that will enhance and expand current NAAT services provided by the Los Angeles County (County) Public Health Laboratory (PHL).

NAAT detects tuberculosis bacteria in specimens one or more weeks earlier than culture. Earlier laboratory confirmation of TB can lead to earlier treatment initiation, improved patient outcomes, increased opportunities to interrupt transmission, and more effective public health interventions. The PHL provides tuberculosis testing services for County public health centers, prison facilities, County hospitals, and other providers. In addition, the PHL provides culture identification for hospitals and commercial laboratories within its jurisdiction. Improvements in PHL NAAT testing will assist the DPH TB Control Program (TBCP) with rapid and appropriate utilization of therapy and infection control.

The objectives of this project are consistent with current progress toward the Center for Disease Control and Prevention performance objectives and turn-around-times. Purchase of equipment and supplies will enable the PHL to: 1) increase the frequency of TB NAAT testing from three to five days a week over the next year; 2) increase the percentage of confirmed and reported TB cases within 48 hours of specimen receipt to 75 percent; 3) increase the number of NAAT tests performed on samples with moderate to high clinical suspicion regardless of smear result; and 4) establish a single NAAT test method for respiratory and non-respiratory specimens which will eventually include molecular resistance screening by sequence analysis. It is expected that increased NAAT testing will improve efficiency and reduce the cost of TB testing by eliminating the use of other screening methods.

Implementation of Strategic Plan Goals

The recommended actions support Goal 4, Health and Mental Health, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

Approval of the recommended actions will allow DPH to accept the APHL Subaward for the period January 1, 2011 through June 30, 2011, in the amount of $114,080. The Subaward will be used to purchase equipment in the amount of $69,300 and services and supplies in the amount of $44,780.

Additional funding for NAAT will be included in future fiscal years, as necessary.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

In 2009, the County reported 706 TB cases representing 6 percent of all cases (11,540) reported in the United States and approximately 30 percent of all cases (2,472) in California. TB testing and treatment is required under California Code of Regulations Title 17.

On November 1, 2010, DPH submitted its application to APHL to receive funding for NAAT.

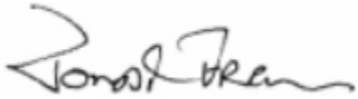
On January 27, 2011, the PHL received the APHL Subaward.

County Counsel has approved Exhibit I as to form. Attachment A is the Grant Management Statement for grants exceeding $100,000.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommended actions will allow the PHL to reduce costs associated with tuberculosis identification and treatment. Also, the TBCP will use the data from the testing to initiate contact investigations sooner, thus reducing the potential exposure of others to tuberculosis.

Respectfully submitted,



JONATHAN E. FIELDING, M.D., M.P.H.
Director and Health Officer

JEF:yl

Enclosures

c: c: Chief Executive Office
County Counsel
Executive Office, Board of Supervisors

EXHIBIT I

APHL

December 10, 2010

Dr. Rosa Pechersky
Los Angeles Department of Public Health
Public Health Laboratory
12750 Erickson Avenue
Downey, CA 90242

Re: Financial Assistance Subaward for TB Nucleic Acid Amplification Testing (NAAT) Improvement and Expansion

Dear Dr. Pechersky:

This letter will confirm the agreement between the Association of Public Health Laboratories, Inc. ("APHL") and Los Angeles Department of Public Health, a nonprofit corporation organized under the laws of California (the "Subrecipient") We agree as follows:

1. **Period of Performance**. This Subaward covers activities for the period of January 1, 2011 (the "Start Date") through June 30, 2011 (the "End Date"). The entire period is referred to as the "Period of Performance".

2. **Background & Purpose**.

A. APHL works to safeguard the public's health by strengthening public health laboratories in the United States and across the world. In collaboration with members, APHL advances laboratory systems and practices, and promotes policies that support healthy communities.

B. Under Cooperative Agreement #1U60HM000803 with the U.S. Centers for Disease Control and Prevention ("CDC") (CFDA#93.065), APHL conducts the APHL-CDC Partnership for Quality Laboratory Practice project to provide technical assistance, training and information to state and local public health and clinical laboratories in controlling communicable diseases, chronic diseases and disorders, and other preventable health conditions.

C. The purpose of this Subaward is to provide a subaward of financial assistance to the Subrecipient for the project described in Exhibit A (which is attached and incorporated by reference) (the "Project").

D. If the Cooperative Agreement is extended or expanded, APHL may consider a role for the Subrecipient in the further activities but is not required to do so.

3. **Financial Assistance**.

A. APHL hereby awards financial assistance to the Subrecipient to support the Project in an amount not-to-exceed one hundred fourteen thousand and eighty US Dollars ($114,080). These funds will be paid in two installments, and subject to the conditions listed below.

i. The funds must be used for costs allowed to APHL by the CDC. [For further information, see Office of Management and Budget ("OMB") Circular A-122, Cost Principles for Non-Profit Organizations, which is currently available at: http://www.whitehouse.gov/OMB/circulars/a122/a122.html.]

ii. The funds awarded must be within the amounts and categories set forth in the Project budget in Exhibit A.

iii. Expenses incurred before the Start Date or after the End Date of this Subaward are not eligible for reimbursement.

iv. Reimbursement of travel expenses is limited to the rates and standards authorized by Los Angeles Department of Public Health policy governing travel by its staff.

B. Eighty percent (80%) of the subaward amount will be distributed to the Subrecipient upon final signature and full ratification of this Subaward. The remaining twenty percent (20%) of the subaward amount will be distributed to the Subrecipient upon receipt and review of the TB NAAT Expansion Project Progress Report, which must be submitted by March 31, 2011.

C. The Subrecipient shall send all Progress Reports to:

Kelly Wroblewski	P: 240-485-2728
8515 Georgia Avenue, Suite 700	F: 240-485-2700
Silver Spring, MD 20910	E: kelly.wroblewski@aphl.org

D. APHL will review and approve or reject each report. APHL may withhold payment until the Subrecipient provides adequate documentation to substantiate appropriate progress. The undisputed portion of each reimbursement request will be paid within thirty (30) days after receipt of the progress report by APHL.

E. The Subrecipient must submit all reimbursement requests to APHL no later than forty-five (45) calendar days after the End Date of this Subaward so that the Subrecipient's expenses may be included in APHL's final report to the CDC. The Subrecipient hereby releases APHL from and waives all claims of any nature for non-payment based upon the Subrecipient's failure to submit all reimbursement requests by this date.

F. APHL is not responsible for payment of any amount other than the financial assistance specifically set forth in this Subaward.

G. If a cost reimbursed under this Subaward is later determined to be unallowable under the Cooperative Agreement, then the Subrecipient shall reimburse APHL for that cost.

4. Responsibilities of the Subrecipient.

A. The Subrecipient shall carry out the Project as described in Exhibit A.

B. The Subrecipient shall assign these staff members to the Project: (i) Dr. Nicole Green, Assistant Laboratory Director.

C. The Subrecipient shall provide APHL with progress and financial reports according to the schedule in the table below. The Subrecipient shall submit one (1) electronic copy, or one (1) unbound copy of each report. The Subrecipient shall prepare reports using a format and software programs agreed to in advance by APHL.

Report	Submission Date
TB NAAT Expansion Project Progress Report	March 31, 2010
TB NAAT Expansion Project Report	July 1, 2011

D. The Subrecipient shall not make any change in the Project that might affect its program or budget without APHL's written approval. These types of changes include (but are not limited to):

i. a change in the project activities or goals;
ii. a change in the individuals serving in the project roles listed above, or a reduction in the amount of time an individual will devote to the project;
iii. a change in the project budget;
iv. use of the funds provided by APHL for a different cost;
v. a change in the project schedule;
vi. a transfer of the funds provided by APHL to another organization (except for the purchase of goods or services for use by the Subrecipient).

E. The Subrecipient shall perform all of its obligations in a timely manner during the Period of Performance, and shall comply with APHL's instructions regarding the closeout process.

F. The Subrecipient shall communicate with the CDC through APHL on all issues pertaining to this subaward. The Subrecipient shall not communicate directly with the CDC about this subaward.

G. Any data provided by the Subrecipient must be free of identifiers that would permit linkages to individuals and must be free of variables that could lead to deductive disclosure of the identity of the individual subjects.

H. The Subrecipient shall comply with all applicable laws in the performance of its project. The Subrecipient shall comply with Federal, State, and local health and safety standards applicable to its operations, and shall establish and implement necessary measures to minimize its employees' risk of injury and illness in activities related to this Subaward. If the Subrecipient is conducting activities outside the US under this Subaward, the Subrecipient shall coordinate as necessary with appropriate government authorities and shall obtain appropriate licenses, permits, and approvals. The Subrecipient shall ensure that it and its officers, directors, employees, agents, and contractors (regardless of nationality) (i) avoid any action that violates or appears to violate any governmental rule relating to ethics and integrity, (ii) avoid any corrupt practice (for example, offering or accepting bribes), and (iii) avoid any fraudulent practice (for example, falsifying financial records). The Subrecipient shall immediately inform APHL of any violation of this provision, and shall cooperate with APHL in taking corrective action.

5. **Compliance with Funding Conditions**. This project is funded through a Cooperative Agreement between APHL and the CDC. The Subrecipient shall comply with the terms and conditions of the Cooperative Agreement. [Further general information may be obtained from the Department of Health & Human Services Grants Policy Statement (dated January 1, 2007) (currently available at: http://www.hhs.gov/grantsnet/adminis/gpd/index.htm).]

A. OMB Circular A-110. The Subrecipient must comply with the financial record-keeping, property management, procurement, and other requirements of Office of Management and Budget ("OMB") Circular A-110, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations. [This is currently available at: http://www.whitehouse.gov/omb/circulars/a110/a110.html.] The regulations adopted by the Department of Health and Human Services to implement the Circular (45 Code of Federal Regulations Part 74) are available at: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=d5241e7268216ffd90acc24c7fcbef67&rgn=div5&view=text&node=45:1.0.1.1.35&idno=45.]

B. Procurement Sources. The Subrecipient shall make positive efforts to include small businesses and minority- and women-owned businesses as suppliers. These efforts must include (but are not limited to) (i) the methods outlined in OMB Circular A-110 §.44(b) and (ii) the methods listed below.

i. Place small, minority, and women-owned business firms on bidders mailing lists;

ii. Solicit these firms whenever they are potential sources of supplies, equipment, construction, or services;

iii. Where feasible, divide total requirements into smaller needs, and set delivery schedules that will encourage participation by these firms; and
iv. Use the assistance of the Minority Business Development Agency of the Department of Commerce, the Office of Small and Disadvantaged Business Utilization, DHHS, and similar state and local offices.

C. Ownership of Property. As between APHL and the Subrecipient, the Subrecipient will own any property acquired with funds provided under this Subaward. The Subrecipient's ownership is subject to the conditions of OMB Circular A-110.

D. Program Income. The Subrecipient shall report to APHL any program income generated by the activities supported by this Subaward, and shall comply with APHL's instructions regarding its disposition.

E. OMB Circular A-133. The Subrecipient must comply with the audit requirements of OMB Circular A-133, Audits of State, Local Governments, and Non-Profit Organizations [This is currently available at: http://www.whitehouse.gov/omb/circulars/a133/a133.html.] The Subrecipient must immediately inform APHL of any adverse audit findings which might impact this Subaward, and shall submit to APHL a copy of its audit report for each year of this Subaward. By signing this Subaward, the Subrecipient certifies that:

i. it is in full compliance with the Single Audit requirements of OMB Circular A-133, or
ii. the Single Audit requirements do not apply because it receives less than $500,000 per year in federal funds.

F. Funding Acknowledgement. When issuing press releases, articles, reports, and other materials describing the project supported by this Subaward, the Subrecipient must clearly state:

i. the percentage of the total costs of the project which will be financed with Federal money;
ii. the dollar amount of Federal funds for the project; and
iii. the percentage and dollar amount of the total costs of the project that will be financed by non-Federal sources.

G. Lower Tier Transactions. The Subrecipient shall include the following provisions of this "Compliance with Funding Conditions" section as conditions of any procurement subcontract (with the vendor agreeing to comply with these provisions as if it is the Subrecipient). These provisions must be conditions of any subcontract, sub-subcontract, etc., governing a lower tier procurement transaction.

H. Public Policy Requirements. The Subrecipient shall comply with the following laws and regulations as applicable to the Cooperative Agreement.

i. Byrd Anti-Lobbying Amendment (31 U.S.C. 1352);
ii. Debarment and Suspension (Executive Orders 12549 and 12689);
iii. Equal Employment Opportunity regulations (Executive Order 11246, as amended by Executive Order 11375 and as supplemented by 41 CFR, Part 60);
iv. Public Health Security and Bioterrorism Preparedness and Response Act (42 U.S.C. 201);
v. Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act ("USA PATRIOT" Act); and
vi. Non-Discrimination Acts, including but not necessarily limited to: (a) Title VI of the Civil Rights Act of 1964 (42 USC 2000[d] *et seq.*) which prohibits discrimination on the basis of race, color or national origin (not applicable to foreign [non-US] organizations); (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex (not applicable to foreign organizations); (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicap (not applicable to foreign organizations); (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§6101-6107), which prohibits discrimination on the basis of age (not applicable to foreign organizations); (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. §§290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) any other nondiscrimination provisions in the specific statute(s) under which the Cooperative Agreement was made; and, (j) the requirements of any other nondiscrimination statute(s) which may apply to the Cooperative Agreement.

I. Bayh-Dole Act: Inventions conceived or first actually reduced to practice by the Subrecipient in the performance of experimental, developmental, or research work under this Subaward are subject to the Bayh-Dole Act (37 CFR 401) and the standard patent right clauses (37 CFR 401.14).

J. Equipment & Products. Purchases of equipment and products under this Subaward are subject to the Buy American Act (41 U.S.C. 10), which requires the purchase of American-made equipment and products to the greatest extent practicable.

K. Travel. Travel within and outside the US under this Subaward is subject to the Fly America Act (49 U.S.C. 40118), which requires utilization of US-flag carriers to the greatest extent practicable (generally regardless of cost, convenience, and personal travel preferences).

L. Publications.

i. Publications shall bear an acknowledgement and disclaimer, as appropriate, such as: "This publication (journal article, etc.) was supported by the Association of Public Health Laboratories and Cooperative Agreement Number #U60/CD303019 from Centers for Disease Control and Prevention ("CDC"). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC."

ii. The US Government has a royalty-free, non-exclusive, and irrevocable right to reproduce, publish, and otherwise use publications, data, and other copyrightable works developed by the Subrecipient under this Subaward. The US Government may also grant a sublicense of these rights to others to do so for Federal purposes.

iii. For the purposes of this section, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.

iv. Any papers published must cite the funding support of all institutes listed below:

National Center for Environmental Health (NCEH)
National Center for Zoonotic, Vector-borne, and Enteric Diseases (CK)
National Center for Immunization and Respiratory Diseases (IP)
National Center for HIV, Viral Hepatitis, STD and TB Prevention (PS)
National Center for Infectious Diseases (ncid) (CID)
Office of the Director, Centers for Disease Control & Prevention (ODCDC)
National Center for Health Marketing (HM)

M. Publicity. Press releases, articles, reports, and other materials publicizing or resulting from the Subrecipient's work under this Subaward must include an acknowledgment that the project was supported by the CDC. The Subrecipient shall use the following disclaimer and acknowledgment of support:

"This publication (journal article, etc.) was supported by the Association of Public Health Laboratories under Cooperative Agreement Number #U60/HM000803 from CDC. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC."

N. APHL Approval Required. The Subrecipient shall not distribute any press releases, articles, reports, or other materials related to this agreement except as approved by APHL in writing. The Subrecipient shall forward one copy of the material to APHL for review. APHL's approval must be obtained prior to distribution. If approved, the Subrecipient shall later forward two (2) copies of the published materials to the

Representative of APHL, who will deliver one (1) of those copies to the CDC. These published materials must be delivered within thirty (30) days after publication.

O. Examination of Records. The Subrecipient shall cooperate with APHL in the audit of APHL that is required by OMB Circular A-133. The Comptroller General of the United States, the Department of Health and Human Services, the CDC, APHL, and their representatives have the right to access and examine any books, documents, papers, and records of the Subrecipient that involve transactions related to this Subaward, for the purpose of audit and making excerpts and transcriptions. The Subrecipient shall maintain auditable records for at least three (3) years following the completion of this Subaward. Further, the Subrecipient shall permit these representatives access to its facilities and personnel for the purpose of on-site inspections, and shall provide information, as requested, to determine compliance with the Cooperative Agreement terms and conditions.

P. Termination of Cooperative Agreement. If funds are not appropriated or otherwise made available for the continued performance of the Cooperative Agreement, or if the Cooperative Agreement is terminated, APHL may terminate this Subaward without penalty upon written notice to the Subrecipient.

Q. Prohibition against Lobbying.

i. The Subrecipient is prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involved conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

ii. In addition no part of CDC appropriated funds, shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

iii. Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or

opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

iv. The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation.

v. It remains permissible to use CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training, and foster safe and healthful environments.

vi. Recipients of CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publications, and "grassroots" activities that relate to specific legislation, recipients of CDC funds should give close attention to isolating and separating the appropriate use of CDC funds from non-CDC funds. CDC also cautions recipients of CDC funds to be careful not to give the appearance that CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

vii. In addition to the restrictions in the Anti-Lobbying Act, CDC interprets the language in the CDC's Appropriations Act to mean that CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.

R. Certifications. By signing this Subaward, the Subrecipient certifies the statements listed below. These certifications are material representations of facts upon which APHL relied when it entered into this transaction.

i. Debarment, Suspension, Ineligibility and Voluntary Exclusion (not applicable to foreign governments or governmental entities, public international organizations, or foreign-government-owned or –controlled entities). The Subrecipient certifies that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

ii. Lobbying. The Subrecipient certifies that:

a. No Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

b. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the Cooperative Agreement supporting this Subaward, the Subrecipient shall complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

iii. No Delinquency on US Government Debts. The Subrecipient certifies that it is not indebted to the United States government, and does not have a judgment lien filed against it.

6. **Consequences of Noncompliance**. If the Subrecipient fails to comply with the terms and conditions of this Subaward or the Cooperative Agreement, APHL may take one or more of the following actions.

A. temporarily withhold reimbursements;
B. deny reimbursement of a noncompliant cost;
C. demand a refund of noncompliant costs already reimbursed;
D. suspend or terminate this Subaward; and
E. take other remedies that may be legally available.

7. **Copyright & Intellectual Property Rights**. The Subrecipient retains all copyright rights to materials developed by it with the funding provided under this Subaward, subject to the provisions of the Section entitled "Compliance with Funding Conditions". The Subrecipient hereby grants to APHL a royalty-free, non-exclusive, and irrevocable right to reproduce, publish, and otherwise use publications, data, and other copyrightable works developed by the Subrecipient under this Subaward for the purpose of furthering the general objectives of the Cooperative Agreement and meeting APHL's obligations under it.

8. **Indemnification**. Neither party to this agreement agrees to indemnify the other party or hold harmless the other party from liability hereunder. However if the common law or a statute provides for either a right to indemnity and/or a right to contribution to any party to this agreement, the right to pursue one or both of these remedies is preserved. \

9. **Representatives**. The following will act as the Representative authorized to administer this agreement on behalf of:

APHL:	Contractor:
Kelly Wroblewski, MPH, MT(ASCP) Manager – HHST Programs 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 P: 240-485-2728 F: 240.485.2700 E: kelly.wroblewski@aphl.org	Dr. Rosa Pechersky, Laboratory Administrator Los Angeles Department of Public Health Public Health Laboratory 12750 Erickson Avenue Downey, CA 90242 P: 562-658-1353 F: 562-401-5999 E: rpechersky@ph.lacounty.gov

10. **Notice**. Any notice that either party is required or may desire to serve upon the other party must be in writing. Notice must be served either (i) personally, (ii) by mail (first class postage prepaid, certified and return receipt requested), or (iii) by delivery through an overnight express service (with confirmed delivery, charge prepaid or billed to shipper). Notice must be addressed as shown below, unless a different address is designated in writing by the receiving party. Notice is also required to be given by telephone, facsimile, and electronic mail on the same date as deposited in the mail or with the express service.

Contractor:	APHL:
Dr. Rosa Pechersky, Laboratory Administrator Los Angeles Department of Public Health Public Health Laboratory 12750 Erickson Avenue Downey, CA 90242 P: 562-658-1353 F: 562-401-5999 E: rpechersky@ph.lacounty.gov	Scott Becker, Executive Director 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 P: 240.485.2745 F: 240.485.2700 E: scott.becker@aphl.org

With a copy to:
Michelle Hanson
Dorn & Hanson, PC
1625 Massachusetts Avenue NW, Suite 450
Washington, DC 20036
P: 202-986-3300
F: 202-986-0823
E: LawFirm@dornhansonlaw.com

11. **Survival**. The obligations and rights of the parties which by their nature would continue beyond the termination or expiration of this Subaward will survive beyond the termination or expiration of this Subaward and remain in full force and effect. These obligations and rights include (without limitation) those set forth in the Sections entitled "Consequences of Noncompliance" and "Indemnification".

12. **Non-Discrimination**. The parties shall not discriminate against any employee or applicant for employment because of race, color, religion, sex, age, national origin, or sexual orientation.

13. **Governing Law**. This Subaward is governed exclusively by the laws of the District of Columbia.

14. **Governing Language**: This English language version of this Subaward is the official version and governs if there is a conflict between this English language version and a foreign translation.

15. **Dispute Resolution**. The parties agree that the sole jurisdiction and venue for any litigation arising from this Subaward is the appropriate federal or District court located in the District of Columbia. The parties hereby waive trial by jury in any action arising out of this Subaward. If a dispute arises, the parties shall make a good faith attempt to resolve the dispute through dialogue and negotiation prior to pursuing court action.

16. **Independent Contractors**. The relationship between the parties to this Subaward is that of independent contractors. This Subaward is not intended to create any association, partnership, joint venture, or agency relationship between the parties.

17. **Assignability**. The Subrecipient shall not assign this Subaward, or any interest in this Subaward, without the prior written consent of APHL.

18. **Successors**. This Subaward will be binding upon, and will inure to the benefit of, the parties and their respective permitted successors and assigns.

19. **Sole Agreement**. This document contains the entire agreement between the parties concerning the subject matter of this Subaward. It supersedes all prior and contemporaneous oral and written understandings.

20. **Amendment**. No amendment of this Subaward will be valid unless in writing and signed by both parties.

21. **Waiver**. A party's waiver of a breach is not to be deemed a waiver of any subsequent breach of the same term or of any other term. No waiver will be valid unless in writing and signed by the waiving party.

22. **Severability**. If any provision of this Subaward is held to be invalid, the remaining provisions of this Subaward are not to be affected and will continue in effect. The invalid provision is to be deemed modified to the least degree necessary to remedy the invalidity.

If this letter correctly states our agreement, please sign one copy in the space below and return it to:

APHL
Attn: Contracts
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910

The second copy is for the Subrecipient's records.

Sincerely,

Carol Clark, MS, CPA
Chieft Operating Officer

Agreed to for Los Angeles Department of Public Health:

By: _____
(Signature of Authorized Contract Officer) (Date)

_____
(Printed Name & Title)

EXHIBIT I

Exhibit A

COUNTY OF LOS ANGELES
DEPARTMENT OF PUBLIC HEALTH
PUBLIC HEALTH LABORATORY

APHL ANNOUNCEMENT:
EXPANSION OF NUCLEIC ACID AMPLIFICATION TESTING FOR TB IN PUBLIC HEALTH LABORATORIES

Contact person: Mary Beth Duke, MS, PHM, Acting Director
Public Health Laboratory
12750 Erickson Avenue
Downey, CA 90242
TEL: 562-658-1350
FAX: 562-401-5999
EMAIL: mduke@ph.lacounty.gov

APPENDIX A. NARRATIVE

A1. DESCRIPTION OF CURRENT TB NAAT SERVICES.

Los Angeles County is home to over 10 million residents and is divided into 8 Service Planning Areas (SPAs). The County supports 11 public health clinics and there are 3 county hospitals that care for tuberculosis patients. In 2009, LAC reported 706 tuberculosis (TB) cases representing 6.1% of all cases (11,540) reported in the United States. Only 4 states (California, Florida, New York, and Texas) reported more TB cases than LAC. Los Angeles County reports approximately one-third (28.6%) of all TB cases (2,472) in California.

The Los Angeles County Public Health Laboratory (PHL) provides Mycobacteriology testing services to county public health centers, prison facilities, and county hospitals. In addition, the PHL provides testing for culture identification to hospitals and commercial laboratories within our jurisdiction. The PHL Mycobacteriology/Mycology section has 17 full-time staff and utilizes automated, molecular, and conventional biochemical methods for the isolation and identification of Mycobacterial species and characterization of mycobacterial genotypes.

Specimens received by the laboratory are logged and entered into the LIMS system. Respiratory and non-respiratory samples are processed by decontamination and concentration and evaluated for

acid-fast bacteria (AFB) using the auramine-rhodamine fluorescent stain method. Smears are reported within 24 hours. Both liquid and solid media are inoculated with processed specimens. NAAT testing is automatically performed on first-time smear positive respiratory specimens and upon special request from Tuberculosis Control Program (TCP). PHL currently uses two NAAT methods, GenProbe Amplified Mycobacterium Tuberculosis Direct (MTD) test and Molecular Beacon, for initial MTB detection and/or characterization. Patient results are reviewed in the laboratory information system (LIMS) to determine testing history, reduce redundant testing, and identify first time tuberculosis positive patients (FTTP).

First-time smear positive respiratory specimens are tested using the MTD test to directly detect the presence of *Mycobacterium tuberculosis* (MTB) complex. MTD is also used for smear-negative patient respiratory samples upon request by the referring physician or TCP if there is high clinical suspicion of disease. The MTD NAAT test has been performed at PHL since 2005 and is now performed three times a week. There are currently 3 microbiologists trained to perform the MTD test. A unidirectional workflow with separate workstations in the TB unit has been designed to minimize potential contamination issues. It takes approximately 6 hours/run to perform MTD test with the current number of samples including controls. Approximately 30% of MTD tests are repeated to rule out specimen inhibition. We have found that differences in protocols used for decontamination and concentration procedures affect performance of the MTD test and currently do not accept referred sediments.

Molecular Beacon TB test is a real-time PCR assay developed by the California Department of Public Health - Microbial Diseases Laboratory (CDPH-MDL). The assay identifies MTB complex and screens for genetic mutations associated with multi-drug resistance. Molecular Beacon is a reflex test performed on smear-positive (2+), MTD positive samples to aid in the rapid determination of resistance to isoniazid (INH) and rifampin (RIF) prior to the reporting of conventional first-line susceptibility testing by MGIT (Mycobacteria Growth Indicator Tube) broth method. The test can also be performed from

solid media or broth culture. Molecular Beacon testing began in June 2008 as a special request test from TCP and has since expanded to include all first-time smear positive/MTD positive patients. The test is performed 3 times a week. There are currently 4 microbiologists trained to perform the Molecular Beacon test. The Beacon test takes approximately 4 hours to perform which includes preparation of nucleic acid, assay preparation, run time, and data analysis.

PHL is also performs additional molecular tests for MTB. The GenProbe AccuProbe test for detection of MTB complex has been in use for over 10 years. AccuProbe is performed on MGIT broth positive samples that are unable to be identified by high-performance liquid chromatography (HPLC) methods. PHL has also performed universal TB genotyping services (MIRU, spoligotyping, IS6110 RFLP) on first-time TB positive patient cultures. PHL has 4 microbiologists trained in use of AccuProbe and 3 microbiologists trained in TB genotyping. In 2009, PHL completed genotyping analysis on 393 patient samples for spoligotyping and 370 samples for MIRU (samples include first time positive cases as well as special genotyping requests by TCP). In October 2009, genotyping was discontinued at PHL and services were transferred to CDPH-MDL. There were 205 patient samples sent to CDPH-MDL for genotyping between Sept – Dec 2009.

The Los Angeles County Department of Public Health (DPH) is responsible for the prevention and control of TB through the Division of Community Health Services (CHS) and the Division of Communicable Disease Control and Prevention (CDCP) under which TCP functions. The majority of patient sputum samples are submitted to PHL from CHS public health centers and the Refugee Assistance Program. Under California and Los Angeles County law, microscopic, culture, immunologic, serologic, or other evidence suggestive of tuberculosis must be reported and positive cultures must be submitted to PHL. TB NAAT services are requested on direct patient specimens and TB isolates. Currently, the most common type of submitter for TB NAAT testing on first-time direct patient specimens are CHS clinics and 1 county hospital. Rapid multi-drug resistance screening using NAAT is

also often ordered by clinical laboratories on known smear-positive patients. We expect that the number of submitters for direct molecular detection and/or resistance testing will increase if PHL becomes a TB NAAT regional laboratory and offers mail-in services.

A2. DESCRIPTION OF FUND UTILIZATION

Combined APHL funds allocated to CDPH-MDL and PHL will be used to purchase equipment and reagents necessary to implement 2 new testing procedures in mycobacteriology and molecular diagnostics. Funds will be used for verification studies and to support initial testing services. Samples for NAAT testing will include routine specimens from Los Angeles County as well as sputum and/or sediments from outside jurisdictions. Improvements in PHL NAAT testing will assist TCP in multiple jurisdictions in regards to rapid and appropriate utilization of therapy and infection control.

PHL plans to begin verification studies and implement IS6110 real-time PCR. This highly sensitive and specific test detects MTB complex. Within a year of implementation, this high-complexity, reference-level laboratory test will expand to include molecular detection and pyrosequencing analysis of gene mutations associated with multi-drug and extremely-drug resistant tuberculosis. These test platforms were chosen to first replace MTD and eventually Molecular Beacon testing and will be used on respiratory and non-respiratory samples in Los Angeles County. Real-time PCR and sequencing will also be used on culture isolates sent in for identification and susceptibility testing.

Measurable objectives for this project will be in-line with our current progress towards CDC/Healthy People performance objectives and turn-around-times. The additional assistance provided by this funding opportunity will allow us to improve on the following aspects of TB laboratory services: 1) Increase frequency of TB NAAT testing from 3 to 5 days a week over the next year, 2) Increase the number of confirmed and reported TB cases within 48 hours of specimen receipt using NAAT from 10% to 75%, 3) Increase the number of NAAT tests performed in Los Angeles County on samples with moderate to high clinical suspicion regardless of smear result, and 4) Establish a single NAAT test

method for respiratory and non-respiratory specimens which will eventually include molecular resistance screening by sequence analysis.

A3. EVALUATION PLAN

Our performance evaluation plan encompasses the following aspects to monitor impact of this award: 1) Maintain a database log to track sample testing which includes submitter and jurisdiction, number of samples and patients tested for NAAT, sample type, method of NAAT test performed, frequency of NAAT testing, smear and culture results associated with NAAT tests, and NAAT positivity rate for MTB, 2) Generate monthly turn around time reports, 3) Participation in proficiency testing, 4) Customer service satisfaction surveys, 5) End of project survey of outside jurisdictions TCP to evaluate impact of mail-in NAAT testing for their TB control efforts.

A4. IMPACT OF TESTING IMPLEMENTATION

PHL and TCP have agreed to work in coordination with CDPH-MDL, California State TB Control branch, and California TB Controllers Association to extend NAAT testing services to jurisdictions beyond Los Angeles County. Discussions are in progress to define criteria, screening procedures, and types of samples accepted for testing from outside jurisdictions utilizing a mail-in service. PHL will accomplish this task with APHL funds ceded to our laboratory by CDPH-MDL (Please see attached letter of intent by Dr. Ed Desmond, Chief of Mycobacteriology, CDPH-MDL). This pilot program will allow PHL to assess feasibility of regional NAAT testing potentially as a fee-based service to sustain high-volume testing.

Pre-screened sputum samples (minimum of 200 or until reagents supplied by APHL are exhausted) that have met agreed criteria for testing will be sent to PHL from smaller public health laboratories that do not have the capacity to perform TB NAAT testing and do not have TB Cooperative Agreements. Mycobacterial culture (and susceptibility) will be performed at the originating public health

laboratory and an additional sputum sample will be sent by overnight courier for NAAT testing. For outside jurisdictions, AFB-positive smear samples will be accepted and tested by NAAT for the presence of MTB complex. Sediments will be accepted if decontamination and concentration procedures are compatible with NAAT testing. Due to budgetary constraints, PHL must have different criteria for outside jurisdiction NAAT testing. For Los Angeles County specimens, both AFB-positive and negative smear samples with moderate to high clinical suspicion will be accepted and tested by NAAT. Specimens for NAAT testing will be prioritized by date received and AFB positive smear result. Laboratory reports will be faxed to a secure fax and/or electronically reported to the submitting physician, local health officer, and local/state TB control program depending on the jurisdiction. NAAT results will allow PHL to reduce costs for susceptibility testing as non-tuberculous mycobacteria will not be set up for testing. In addition, first-line sensitivity testing may be bypassed if resistance is detected by sequence-based analysis. NAAT results will be used by TBC to determine appropriate treatment regimens. Also, TBC will use this data to determine if there has been a shorter time to treatment and if contact investigations have been initiated sooner. No legal or regulatory advantages or barriers are expected.

PHL works closely with TCP and increased NAAT testing will help TBC and PHL reach performance objective measures. Evaluation plan data collected from PHL NAAT testing will be discussed at PHL-TCP liaison meetings held approximately every 2 months. Discussions will include if NAAT testing has decreased time to treatment initiation and/or impacted contact investigations in a positive manner. Data generated from NAAT testing will be included in the mid-term and final report for our county's Tuberculosis Elimination and Laboratory Program Cooperative Agreement as well as required APHL reports.

APPENDIX B. BUDGET

The following budget plan reflects the combined award to CDPH-MDL ($52,301) and LAC-PHL ($62,260) for a total potential award amount of $114,561. We are requesting assistance in the amount of $114,080.

EQUIPMENT- $69,300		
ABI 7500 Fast DX Real-Time PCR platform	$65,900	Needed for IS6110-based molecular detection of MTB complex
Benchtop autoclave	$3,000	Needed to prepare DNA template from culture isolates for verification assays and from culture samples
E-gel electrophoresis platform	$400	Needed to confirm PCR product from real-time PCR for pyrosequencing analysis of genes associated with antibiotic resistance

SUPPLIES - $29,250		
Roche RT PCR kits	$6,000	Needed for IS6110-based molecular detection of MTB complex
GenProbe MTD kits	$5,000	Needed for comparison during verification assay for molecular detection of MTB complex
Taq polymerase and dNTPs	$4,000	Needed for pyrosequencing for molecular detection of resistance genes
PSQ reagent kits	$6,000	Needed for pyrosequencing for molecular detection of resistance genes
BD Geneohm lysis kits	$1,200	Needed to prepare DNA template from respiratory and non-respiratory samples for real-time PCR
Primers/probes	$2,000	Needed for IS6110-based molecular detection of MTB complex and pyrosequencing

Media and additives	$1,950	Needed for culture based comparison during verification assay for molecular detection of MTB and resistance gene mutation
SIRE antibiotics	$400	Needed for culture based comparison during verification assay for molecular detection of resistance genes
E-gels and DNA markers	$2,300	Needed to confirm PCR product from PCR for pyrosequencing analysis of genes associated with antibiotic resistance
Plasmid prep kit and competent cells	$400	Needed to prepare and maintain stock of inhibition plasmid control for real-time PCR

OTHER - $15,530

3 yr PM/Service contract on ABI7500 Fast DX	$9,230	Needed for IS6110-based molecular detection of MTB complex to maintain CLIA-compliance
Travel for training	$3,000	Needed to assist in developing pyrosequencing assay targets
1 yr PM/service on Perkin Elmer 9700 PCR thermocycler	$1,300	Needed for pyrosequencing assay to maintain CLIA-compliance
Sanger sequencing send outs	$1,500	Needed for confirmation of mutations associated with antibiotic resistance detected by pyrosequencing
TB proficiency test samples	$500	Needed for personnel competency

TOTAL REQUESTED FINANCIAL ASSISTANCE $114,080

APPENDIX C. EXPANSION OF TB NAAT SUB-GRANT REQUIRED DATA FORM

1. Number of clinical specimens (e.g., sputum, CSF, biopsy, etc.) on which NAAT for the direct detection of *M. tuberculosis* complex from a clinical specimen was performed or referred:					
Total Number 2008	266[a,b]	Total Number 2009	379[a]	Total Number 2010 (Jan.-June)	211[a]
2. Number of clinical specimens (e.g., sputum, CSF, biopsy, etc.) on which molecular testing for TB drug resistance was performed or referred:					
Total Number 2008	91[a]	Total Number 2009	100[a]	Total Number 2010 (Jan.-June)	125[a]
3. Number of individual patients for whom a clinical specimen (e.g. , sputum, CSF, biopsy, etc.) was processed and a TB Culture was inoculated:					
Total Number 2008	3768	Total Number 2009	3363	Total Number 2010 (Jan.-June)	2037
3a. Of these, report the number of individual patients for whom at least one culture was positive for *M. tuberculosis* complex:					
Total Number 2008	308	Total Number 2009	221	Total Number 2010 (Jan.-June)	99
4. Number of individual patients from your jurisdiction for whom a clinical specimen (e.g., sputum, CSF, etc.) was tested directly with a NAAT. [This includes testing performed in-house and referred testing] [This does not include testing conducted in your laboratory on specimens referred from outside of your jurisdiction][This does NOT refer to rapid species identification tests (i.e. ACCUPROBE)]:					
Total Number 2008	266	Total Number 2009	379	Total Number 2010 (Jan.-June)	193
4a. Of these, report the number of individual patients for whom a NAAT or other rapid detection test was positive for *M. tuberculosis* complex:					
Total Number 2008	143[b]	Total Number 2009	145	Total Number 2010 (Jan.-June)	107
5. Number of of individual patients that were reported positive for the identification of *M. tuberculosis* complex by NAAT from a clinical specimen within 48 hours of specimen receipt:					
Total Number 2008	19[c]	Total Number 2009	116[c]	Total Number 2010 (Jan.-June)	71[c]

[a] Laboratory data recorded as number of individual patients not clinical specimens

[b] Calculations based on TRIMS registry data as of 8/2009

[c] Data estimate

State of California—Health and Human Services Agency
Department of Public Health

Mark B Horton, MD, MSPH
Director

ARNOLD SCHWARZENEGGER
Governor

November 18, 2010

Nicole Green
Los Angeles County Public Health Laboratory
12750 Erickson Ave.
Downey, CA 90242

Dear Dr. Green,

This letter is to express support for your application for funding of increased and enhanced use of nucleic acid amplification (NAA) testing for Mycobacterium tuberculosis.

We at the California Department of Public Health had been encouraged to apply for funding for the same purpose, in the amount of $52,301. Due to financial problems of California State government, we are unable to utilize those funds as intended by the Association of Public Health Laboratories (APHL) and the U.S. Centers for Disease Control and Prevention (CDC). We therefore request that APHL award this $52,301 to the Los Angeles County Public Health Laboratory, for the purpose of making enhanced and increased NAA testing available to health jurisdictions in California other than Los Angeles County. We understand that a minimum of 200 specimens will be accepted and tested by the Los Angeles County Public Health Laboratory from outside public health jurisdictions. It is our further understanding that every effort will be made to test these specimens in a manner to meet the turnaround time standard of Healthy People 2010 number 14.14, namely to report results for 75% of specimens within two days of receipt in the laboratory.

I wish you success in your endeavors,

Sincerely,

Edward P. Desmond

Edward P. Desmond, Ph.D., D(ABMM)
Chief, Mycobacteriology and Mycology Section

Microbial Diseases Laboratory Branch, Division of Communicable Disease Control, 850 Marina Bay Parkway, Richmond, CA 94804
(510) 412-3781
Internet Address: WWW.CDPH.CA.GOV

Attachment A

Los Angeles County Chief Executive Office
Grant Management Statement for Grants Exceeding $100,000

Department: Public Health – Public Health

Grant Project Title and Description
TB Nucleic Acid Amplification Testing(NAAT) - to improve and expand the TB NAAT.

Funding Agency	Program (Fed. Grant #State Bill or Code #)	Grant Acceptance Deadline
Association of Public Health Laboratories, Inc.	Subaward	N/A

Total Amount of Grant Funding: $ 114,080 County Match Requirements: N/A

Grant Period: Begin Date: January 1, 2011 End Date: June 30, 2011

Number of Personnel Hired Under this Grant: None Full Time Part Time

Obligations Imposed on the County When the Grant Expires

Will all personnel hired for this program be informed this is a grant funded program? Yes ☒ No ☐

Will all personnel hired for this program be placed on temporary "N" items? Yes ☒ No ☐

Is the County obligated to continue this program after the grant expires Yes ☐ No ☒

If the County is not obligated to continue this program after the grant expires, the Department will:

a). Absorb the program cost without reducing other services Yes ☐ No ☒

b). Identify other revenue sources Yes ☐ No ☒

(Describe)

c). Eliminate or reduce, as appropriate, positions/program costs funded by this grant Yes ☒ No ☐

Impact of additional personnel on existing space: None.

Other requirements not mentioned above: None

Department Head Signature [signature] Date 4.4.11